In re Application of: Niva SHAPIRA et al
Serial No.: 10/543,022
Filed: September 14, 2006
Office Action Mailing Date: February 12, 2010

Examiner: Audrea BUCKLEY
Group Art Unit: 1611
Attorney Docket: 32467
Confirmation No.: 4059

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1 and 63-87 are in this Application. Claims 82-87 have been withdrawn from consideration for being directed to non-elected inventions. Claims 69-73 have been withdrawn from consideration for being directed to non-elected species.

Claims 1, 66, 68, 74, 76 and 79-81 have been rejected under 35 U.S.C. § 102. Claims 1, 63-68 and 74-81 have been rejected under 35 U.S.C. § 103.

Claims 2-62 have been canceled in a previous response. Claims 67, 71-73 and 76 have been canceled herewith. Claims 1, 75, 77 and 78 have been amended herewith.

Amendments To The Claims

35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner has stated that claims 1, 67 and 75-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 67 and 76 have been canceled. Claims 1, 77 and 78 have been amended.

Specifically, in one particular, the Examiner has stated that claims 1 and 67 are vague and indefinite because the metes and bounds of the term "sufficient" are unclear, and the instant specification does not define the subjective term "sufficient" in any limiting way.

Claim 1 has been amended so as to recite (with regard to the antacid) "a dose capable of elevating the pH in stomach by at least one pH unit" instead of "a dose sufficient to elevate pH in a stomach". The dose of antacid is therefore defined in a clear and quantitative manner which can be readily determined by one of ordinary skill in the art.

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Claim 1 has been further amended so as to recite (with regard to the antioxidant) "wherein the relative amount of the antioxidant in the composition is from 10 to 95% w/w of the total antacid and antioxidant weight" instead of "in a dose sufficient to decrease free radical generation in the stomach". The dose of antioxidant is therefore defined in a clear and quantitative manner, via reference to the abovementioned dose of antacid.

The amendments to claim 1 are supported by claims 67 and 76. Accordingly, claims 67 and 76 have been canceled.

In another particular, the Examiner has stated claims 75-78 are indefinite because the metes and bounds of the terms "from about" and "to about" are unclear.

Claims 77 and 78 have been amended so as to no longer recite the term "about".

As discussed hereinabove, claim 76 has been canceled. The limitations previously recited in claim 76 have been introduced into amended claim 1 without reciting "about".

Claim 75 does not recite the term "about". Applicant therefore believes that the rejection of this claim is erroneous.

Applicant therefore believes to have overcome the Examiner's rejections.

35 U.S.C. § 102 Rejections

The Examiner has stated that claims 1, 66, 68, 74, 76 and 79-81 are rejected under U.S.C. § 102(b) as being anticipated by Lambert et al. as evidenced by Handelman et al. The Examiner's rejection is respectfully traversed. Claim 76 has been canceled without prejudice. Claim 1 has been amended.

Specifically, the Examiner has stated that Lambert et al. teach an antacid formulation comprising an antacid or mixture of antacids, oil, an antioxidant and a carrier. The Examiner has further stated that Lambert et al. teach a formulation comprising 14.1 % rolled oats, and that Handelman et al. teach that several classes of compounds with antioxidant activity have been identified in oats.

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Lambert et al. teach a use of 0.02-1.0 % antioxidant, preferably ethoxyquin, in an antacid formulation comprising 11.0-45.0 % antacid, whereby the antioxidant is added in order to prevent breakdown of certain components of the formulation prior to consumption of the formulation (see, for example, column 2, lines 48-54, and column 3, lines 9-13, of Lambert et al.).

With respect to the Examiner's statements that Lambert et al. teach a formulation comprising 14.1 % rolled oats, and that Handelman et al. teach that several classes of compounds with antioxidant activity have been identified in oats, Applicant wishes to note that Handelman et al. do not teach that rolled oats are an antioxidant.

Rather, Handelman et al. teach that oat fractions comprise an antioxidant capacity equivalent to about 2-8 μmol/g of Trolox, and that most of the antioxidants in the oat fractions are phenolics such as caffeic acid (molecular weight = 180) and ferulic acid (molecular weight = 194). See, for example, the Materials and Methods section; page 4890, Table 2; and the paragraph bridging pages 4891 and 4892, in Handelman et al. Thus, the teachings of Handelman et al. indicate that antioxidants comprise a very small fraction (e.g., less than 0.1 %) of the weight of oats. Furthermore, Handelman et al. teach that steam treatment reduces the antioxidant capacity of oats (see, for example, final paragraph of page 4890, therein).

It is to be noted that it is well known that many foods, including oat, reduce stomach acidity. It is therefore clear that oat is merely taught as another food that will reduce stomach acid and not as an ingredient for use in combination with antiacid for reducing the damaging effect of over-acidity and related facilitated-oxidative state in the stomach.

Hence, as evidenced by Handelman et al., even if the formulation taught by Lambert et al. comprises 20 % steam-rolled oats, the amount of antioxidants in the oats would represent a negligibly small fraction of the formulation.

In view of the above, it is clear that Lambert et al. teach a use of only a small amount of antioxidant, e.g., up to 1 % of the formulation, and less than 10 % of the

total weight of antioxidant and antacid. Such a small amount of antioxidant is consistent with the intended use of an antioxidant as taught by Lambert et al., i.e., merely preventing breakdown of certain components of the antacid formulation.

In sharp contrast, claim 1 relates to a composition for potentiating antioxidative activities, which comprises substantial proportions of both antacid and antioxidant, such that the amount of the antioxidant in the composition is at least 10 %, but no more than 95 %, of the total weight of antacid and antioxidant.

Lambert et al. neither teach nor suggest a composition with an antacid and an antioxidant in such proportions.

Applicant therefore contends that claim 1, as well as claims 66, 68, 74 and 79-81, which depend directly or indirectly therefrom, are not anticipated by Lambert et al. as evidenced by Handelman et al., and are therefore allowable.

35 U.S.C. § 103 Rejections (Lambert et al.)

The Examiner has stated that claims 1, 63, 64, 66-68, 74, 76 and 79-81 are rejected under U.S.C. § 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al. The Examiner's rejection is respectfully traversed. Claims 67 and 76 have been canceled without prejudice. Claim 1 has been amended.

Specifically, the Examiner has described the teachings of Lambert et al. and Handelman et al. as above, and further stated with respect to claims 63 and 64 that the capability of decreasing free radical and peroxide generation as in claim 63 and the ability to decrease at least two-fold the concentration of free radicals and peroxides as in claim 64 are result effective variables because changing them clearly will affect the type of product obtained, that discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art, and that it would have been obvious to utilize appropriate quantities of the antioxidant and antacid components in order to control the potency and efficacy of the antacid formulation, so as to produce desired end results.

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As discussed hereinabove, Lambert et al. fail to teach a composition with an antacid and an antioxidant in the proportions recited in claim 1.

Furthermore, the object of the formulation taught by Lambert et al. is to provide relief from excess gastric acid, particularly in horses (see, for example, column 1, lines 52-62, therein).

Lambert et al. teach a use of a small amount (0.02-1.0 %) of antioxidant, preferably ethoxyquin, for a specific purpose, i.e., in order to prevent breakdown of certain components of the formulation prior to consumption of the formulation (see, for example, column 2, lines 48-54, and column 3, lines 9-13, of Lambert et al.). Lambert et al. do not even remotely suggest that the antioxidant may have another purpose. Moreover, Lambert et al. do not even remotely suggest that inclusion of more than 0.02-1.0 % of antioxidant may be beneficial for achieving the purpose taught therein, i.e., preventing breakdown of certain components of the formulation. Indeed, Lambert clearly teach that the beneficial range is 0.02-1.0 % antioxidant, and not more than 0.02-1.0 %.

Thus, Lambert et al. do not provide any motivation for including more than 0.02-1.0 % antioxidant, as Lambert et al. teach that 0.02-1.0 % antioxidant is an appropriate range for the purposes taught therein. Moreover, the Examiner has not provided any evidence or explanation suggesting that 0.02-1.0 % is not an optimal range of antioxidant concentration in an antacid formulation designed for providing relief from excess gastric acid.

As discussed hereinabove, a range of 0.02-1.0 % antioxidant in the formulation taught by Lambert et al. results in a proportion of antioxidant which is outside the scope of the claims (e.g., less than 10 % of the total weight of antioxidant and antacid).

In sharp contrast, embodiments of the present invention include antioxidant-containing compositions for providing protection of cells in the body from oxidative damage, the compositions further comprising an antacid, which surprisingly increases

the antioxidant activity of the composition (see, for example, page 3, lines 1-7 and 15-20, of the instant application).

Thus, the intended activity of compositions according to embodiments of the present invention (preventing oxidative damage) is different than the intended activity of the formulations taught by Lambert et al. (antacid). In addition, the intended purpose of the antioxidant according to embodiments of the present invention (preventing oxidative damage in the body) is different than the purpose taught by Lambert et al. (preserving formulation components prior to consumption).

The use of antioxidant in order to prevent breakdown of components of a formulation, as described by Lambert et al., cannot be assumed to require the same proportions of antioxidant required for use of an antioxidant as an active ingredient in a composition, as in embodiments of the present invention.

Hence, if one of ordinary skill in the art were to modify the antacid formulation of Lambert et al. as suggested by the Examiner, by searching for an optimum value of quantities of antioxidant and antacid components, in order to control the potency and efficacy of the antacid formulation, so as to produce desired end results, there is no reason to expect that he would arrive at quantities different than those taught by Lambert et al., let alone arrive at the quantities recited in the instant claims. Thus, contrary to the Examiner's statements, the claimed subject matter cannot be arrived at by merely discovering an optimum value of a result-effective variable for the teachings of Lambert et al., and hence without an inventive activity.

The quantities of antioxidant and antacid recited in the instant claims, which include a higher proportion of antioxidant than taught by Lambert et al., are selected to be suitable for a composition for providing protection of cells in the body from oxidative damage (e.g., from free radicals and peroxides), not for an antacid formulation *per se*. One of ordinary skill to in the art would have no motivation to convert the antacid formulation of Lambert et al. into a composition for providing

protection of cells in the body from oxidative damage, by increasing the proportion of antioxidant therein.

Applicant therefore contends that claim 1, as well as claims 63, 64, 66, 68, 74, and 79-81 which depend directly or indirectly therefrom, are not rendered obvious over Lambert et al. as evidenced by Handelman et al., and are therefore allowable.

35 U.S.C. § 103 Rejection (Lambert et al. in view of Grimberg)

The Examiner has stated that claim 67 is rejected under U.S.C. § 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al., as applied to claims 1, 63, 64, 66-68, 74, 76 and 79-81, and further in view of Grimberg.

The Examiner's rejection is respectfully traversed. Claim 67 has been canceled without prejudice, thereby rendering the rejection moot.

Notwithstanding the above, the Examiner's rejection is discussed below in view of the incorporation of subject matter from claim 67 into amended claim 1.

Specifically, the Examiner has stated that Grimberg teaches an antacid composition, and it is noted therein that the pH is increased by at least one pH unit, as required by the instant claim.

As discussed hereinabove, Lambert et al. neither teaches nor suggests use of a relatively large proportion of antioxidant.

Grimberg et al. does not even remotely suggest a use of a relatively large proportion of antioxidant.

Applicant therefore submits that the patentability of the claimed subject matter is not affected by Lambert et al. in view of Grimberg.

35 U.S.C. § 103 Rejection (Lambert et al. in view of Howard et al.)

The Examiner has stated that claims 65, 75, 77 and 78 are rejected under U.S.C. § 103(a) as being unpatentable over Lambert et al. as evidenced by Handelman et al., as applied to claims 1, 63, 64, 66-68, 74, 76 and 79-81, and further in view of

Howard et al. The Examiner's rejection is respectfully traversed. Claims 77 and 78 have been amended.

Specifically, the Examiner has stated that Howard et al. teach a flavonol-containing composition wherein at least 25 % of the composition includes polyphenols, and at least 1 % is flavonol, and that Howard et al. teach a polyphenol content with overlaps with the range recited in claim 78. The Examiner has further stated that it would have been obvious to include the polyphenol and flavonol antioxidants disclosed by Howard et al. into the formulation of Lambert et al., which also teach the benefits of the antioxidant component, that all of the formulations are to be taken orally as a health benefit, that Lambert et al. teach that an antioxidant benefits the antacid formulation by preventing oxidation of certain components prior to consumption, and that the skilled artisan would have been motivated to implement the polyphenol antioxidants for the reasons deemed desirable by Howard et al.

As discussed in detail below, Applicant contends that:

a) the ranges taught by Howard et al. do not overlap the ranges recited in the claims, despite the Examiner's statements to the contrary;

b) none of the cited art suggests using a proportion of antioxidant recited in the claims; and

c) there is no motivation to combine the teachings of Howard et al. and Lambert et al.

A. The ranges taught by Howard et al. do not overlap the ranges recited in the claims

Claim 1, from which 65, 75, 77 and 78 depend, recites a range of 10 to 95 % (w/w) for the amount of the antioxidant in the composition relative to the total antacid and antioxidant weight. Claims 77 and 78 recite additional ranges for the same variable.

Howard et al. teach a composition comprising polyphenols, at least some of which are antioxidants, but do not even remotely suggest the presence of an antacid. Thus, the composition taught by Howard et al. contains no antacid, and the relative

amount of antioxidant is therefore always 100 % of the total antacid and antioxidant weight, regardless of the exact concentration of polyphenols in the composition.

The "range" of 100 % for the abovementioned variable is clearly outside the scope of claim 1. Hence, there is no overlap in ranges between the teachings of Howard et al. and the claimed embodiments of the invention.

B. The cited art fails to suggest using a proportion of antioxidant recited in the claims

As discussed hereinabove, Lambert et al. teach a use of only a small amount of antioxidant in the antacid formulation described therein (e.g., up to 1 % of the formulation, and less than 10 % of the total weight of antioxidant and antacid), and the teachings of Lambert et al. are therefore outside the scope of the claims. As further discussed therein, the small amount of antioxidant taught by Lambert et al. is consistent with the intended use of an antioxidant for merely preventing breakdown of certain components of the antacid formulation.

Even if one of skill in the art were motivated to include the polyphenols described by Howard et al. as an antioxidant in the antacid formulation of Lambert et al., which Applicant disputes, the result would still be an antacid formulation with only a small amount of antioxidant, which would be outside the scope of the claims.

Moreover, to the best of Applicant's understanding, the Examiner has not alleged that Howard et al. provides motivation to increase the proportion of antioxidant in an antacid formulation.

C. There is no motivation to combine the teachings of Howard et al. and Lambert et al.

As discussed hereinabove, Lambert et al. teach an antacid formulation intended to provide relief from excess gastric acid, particularly in horses. Howard et al. teach a composition designed to prevent coronary heart disease (CHD) and stroke (see, for example, column 9, lines 11-26, in Howard et al.). As there is no connection between the potential health benefits provided by the teachings of Lambert et al. and Howard et al., one of skill in the art would have no motivation to combine a

polyphenol composition taught by Howard et al. with an antacid formulation taught by Lambert et al. Rather, one of skill in the art would recognize that the difference in potential health benefits indicates that the antacid and polyphenol composition will be administered to different sets of subjects, with different dosing regimens, and therefore there is no advantage to combining the antacid and polyphenols.

In sharp contrast, the claimed embodiments of the invention are based on the previously unknown and unsuspected ability of antioxidants and antacids to act together synergistically to prevent oxidative damage in a body (e.g., in a stomach).

Moreover, one of skill in the art would have no motivation to include a polyphenol described by Howard et al. as an antioxidant in the antacid formulation of Lambert et al., because the antioxidant in the formulation of Lambert et al. is intended to preserve components of the formulation prior to consumption. Although Howard et al. describe various physiological effects of the composition taught therein, Howard et al. fail to teach or suggest that the polyphenols described therein are suitable for preserving products prior to consumption.

Moreover, many antioxidants are in general commercial use as food additives which prevent deterioration prior to consumption (including the ethoxyquin taught by Lambert et al.). One of skill in the art would, if searching for an alternative to ethoxyquin, select a food additive known to be effective for the intended purpose of preventing deterioration prior to consumption, rather than a polyphenol described by Howard et al., which Howard et al. fail to teach or suggest is effective for such a purpose.

In addition, one passage of Howard et al. cited by the Examiner (i.e., column 7, lines 14-16) merely teaches a relatively convenient manner for obtaining polyphenols from red wine. The passage does not suggest that polyphenols may be more conveniently obtained than other antioxidants.

Another passage of Howard et al. cited by the Examiner (i.e., column 13, lines 4-7) suggests that wine polyphenols reduce LDL oxidation in plasma. However, this conclusion is based on results of daily administration of substantial amounts of

polyphenols, specifically, 1 gram per day of polyphenol powder for 1 year (see, for example, column 11, lines 15-65, and column 15, lines 35-45, of Howard et al.). There is no evidence that any health benefits would result if polyphenols were included at the low concentrations suitable for an antioxidant additive in an antacid formulation (e.g., 0.02-1.0 %), as described by Lambert et al.

In view of the above, Applicant submits that the cited art does not teach all of the limitations recited in claim 1, let alone claims depending from claim 1, either alone or in combination.

Applicant therefore contends that claims 65, 75, 77 and 78 are not rendered obvious over Lambert et al. as evidenced by Handelman et al., in view of Howard et al., and are therefore allowable.

Additional Amendments

Claim 75 has been amended in order to improve the readability thereof.

The term "diuterpenes" has been corrected to "diterpenes". This amendment is a correction of an obvious typographical error.

A space has been inserted between the terms "and" and "sesquiterpenes".

Superfluous spaces following the terms "stilbenes" and "sesquiterpenes" have been deleted.

The phrase "mono and sesquiterpenes" has been amended to "monoterpenes and sesquiterpenes".

The above amendments are purely cosmetic and do not affect the scope of the claims.

In addition, withdrawn claims 71-73 have been canceled without prejudice.

Examination of Generic and Non-Elected Claims

In view of the amendments made to the claims and the arguments recited herein it is believed that the claims are allowable with respect to the elected species

and hence examination of all claims in this Application in their generic context and with respect to all the species recited therein is respectfully requested.

In view of the above amendments and remarks it is respectfully submitted that claims 1, 63-66, 68-70, 74, 75 and 77-81 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Enclosures:

- Petition for Extension (3 Months)